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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/639,050	08/11/2003	Sascha Zarins	412692000901	6741
34263	7590	11/22/2005		
O'MELVENY & MYERS LLP 610 NEWPORT CENTER DRIVE 17TH FLOOR NEWPORT BEACH, CA 92660			EXAMINER MARMOR II, CHARLES ALAN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TW

<b>Office Action Summary</b>	Application No. 10/639,050	Applicant(s) ZARINS ET AL.	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 48-62 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48-57 is/are allowed.
- 6) ☒ Claim(s) 58,59,61 and 62 is/are rejected.
- 7) ☒ Claim(s) 60 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>11182005</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____.  |

### **DETAILED ACTION**

1. This Office Action is responsive to the Amendment filed October 24, 2005. The Examiner acknowledges the amendments to claims 53 and 55 and the addition of new claims 58-62. Claims 48-62 are pending.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 58, 59 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaldany ('599). Kaldany teaches a method for delivering a marker or agent to a tissue site or body cavity, such as a biopsy cavity. The delivery device (100) includes a tube (104) having a lumen (104c) therethrough and a side exit port (104b); a rod (108) slideably located in the lumen of the tube; an agent or tissue marker (106) removably located at the distal end of the tube; and an intermediate member (105) that forms a flexible covering separating the rod from the tissue marker. The delivery device is advanced to the biopsy cavity where the rod is actuated to displace a portion of the intermediate portion of the delivery device and deposit a tissue marker through the side exit port into the biopsy cavity. A fluid (107a) may be provided in the tube

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lumen between the rod and the intermediate member where displacement of the rod in a distal direction displaces the fluid to displace the intermediate member.

4. Claims 58 and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Fisher ('244). Fisher teaches a method for marking a biopsy cavity using a delivery device. The delivery device (10) includes a tube (24) having a lumen therethrough and a side exit port (26) adjacent a distal end thereof; a rod (18) slideably located in the lumen of the tube; a tissue marker (16) removably located at the distal end of the tube; and an intermediate member (15) that forms a flexible covering separating the rod from the tissue marker. The delivery device is advanced to the biopsy cavity where the rod is actuated to displace a portion of the intermediate portion of the delivery device and deposit a tissue marker through the side exit port into the biopsy cavity.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany ('599) in view of Wang et al. ('494). Kaldany, as discussed hereinabove, teach all of the limitations of the claim except that the flexible polymeric covering includes PET. Wang et al. teach that PET is a polymeric material that is known in the medical arts to be useful for its flexibility and softness

(see column 7, lines 31-36). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use PET to make the flexible cover membrane in a delivery device similar to that of Kaldany in view of the teachings of Wang et al. in order to provide the flexible membrane with a desired flexibility and softness.

***Allowable Subject Matter***

7. Claims 48-57 are allowed over the prior art of record.
8. Claim 60 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
9. The following is a statement of reasons for the indication of allowable subject matter:  
  
Regarding claims 48-52, no prior art of record teach or fairly suggest a tissue marker delivery device including a distally extending tube; a rod located within the tube lumen; an intermediate member separating the rod from a marker disposed in a marker seat in the distal end of the tube; and a deployment lock having a portion removably attached to the tube to engage a portion of the rod in order to prevent distal movement of the rod such that the rod is prevented from prematurely deploying the marker.  
  
Regarding claims 53-57 and 60, no prior art of record teach or fairly suggest a method for marking a biopsy cavity, as claimed by Applicant, where a deployment lock having a portion

removably attached to the tube such that the deployment lock contacts the rod to prevent the rod from moving is unlocked prior to the step of actuating the rod.

***Response to Arguments***

10. Applicant's arguments, see page 7 of the Remarks, filed October 24, 2005, with respect to the rejection of claims 53, 54 and 56 under 35 USC 102(b) as being anticipated by Kaldany; the rejection of claim 57 under 35 USC 103(a) as being unpatentable over Kaldany in view of Wang; and the rejection of claims 53 and 56 under 35 USC 102(e) as being anticipated by Fisher have been fully considered and are persuasive. The rejections of claims 53-57 have been withdrawn.

11. Applicant's arguments filed October 24, 2005 regarding new claims 58-62 have been fully considered but they are not persuasive.

Applicant contends that Fisher does not describe a delivery device with a side exit port. The Examiner respectfully disagrees. Such a feature is illustrated in Figure 2 of the Fisher patent. Reference character 26 denotes the side exit port.

Applicant further contends that Kaldany does not describe a tissue marker. The Examiner respectfully disagrees. Absent any special definition for the term "tissue marker" set forth in the specification of the instant application, the biological agents or drugs of Kaldany may be broadly considered to mark the tissue site.

*Conclusion*

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

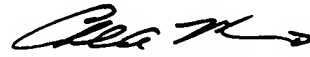
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II  
Primary Examiner  
Art Unit 3736

cam  
November 18, 2005